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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,807	01/28/2002	Frank Popovsky	P40.2-9585	8984

490 7590 06/30/2004

VIDAS, ARRETT & STEINKRAUS, P.A.  
6109 BLUE CIRCLE DRIVE  
SUITE 2000  
MINNETONKA, MN 55343-9185

EXAMINER

KENNEDY, SHARON E

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/701,807

Applicant(s)

POPOVSKY, FRANK

Examiner

Sharon Kennedy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 6.10.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_.

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### **DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action or the MPEP.

#### ***Specification***

The disclosure is objected to because of the following informalities:  
Applicant should insert a "Reference to Related Applications" section to show that this application is a continuation of the PCT application.

Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

Claims 32-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 32 and 33 are indefinite because they are method claims dependent upon an article claim. The PTO prefers that these be put into independent form.

#### ***Claim Rejections - 35 USC § 102***

Claims 1-13, 15, 16, 34 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Kimber et al., WO 96/14100. Kimber shows the frangible closure 4. Regarding embodiments to the needle-fitting, note page 3, lines 25+, wherein the closure end of the syringe may be fitted with a hypodermic needle. Regarding claims 11-12, it does not appear that Kimber expressly discloses the

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claimed dimensions, however, judging from the figures, it appears that the Kimber device is well within the claimed ranges.

Claims 1 and 14 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Bitdinger, US 5,250,037.

Claims 1-13, 15-17, 21-30, 32-34 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Kimber, WO 92/12746. See especially Figure 6, end 27.

***Claim Rejections - 35 USC § 103***

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kimber et al., WO 96/14100. It would be obvious to enclose the Kimber device in a wrapper since that is how all pre-filled syringes are shipped.

Claims 18-20, 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kimber et al., WO 92/12746. Regarding claims 18-20, it does not appear that Kimber expressly discloses the claimed dimensions, however, judging from the figures, it appears that the Kimber device is well within the claimed ranges, or such ranges would be an obvious design choice dependent upon the environment of use of the syringe. Regarding claim 31, it would be obvious to enclose the Kimber device in a wrapper since that is how all pre-filled syringes are shipped.

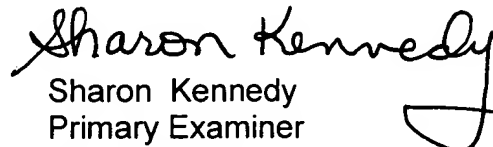
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***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Kennedy whose telephone number is 703/305-0154. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703/308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Sharon Kennedy  
Primary Examiner  
Art Unit 3762

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